MAR 15 2006

K060328

510K) SUMMARY

DATE
February 7, 2006

PRODUCT, CLASSIFICATION NAME
Trade name: Planmeca Promax 3D
Common name: Panoramic/Tomography x-ray system
Classification: 76 EHD, Class II
Regulation number: 872.1800

MANUFACTURER
Planmeca Oy
Asentajankatu 6
FI-00880 Helsinki, Finland
Phone: +358 20 7795 500
Fax: +358 20 7795 396
Contact person: Lars Moring

UNITED STATES SALES REPRESENTATIVE (U.S. DESIGNATED AGENT)
Planmeca USA Inc.
100 North Gary Avenue, Suite A
Roselle, IL 60172
Phone: (630) 529 2300
Fax: (630) 529 1929
Contact person : Bob Pienkowski

INTENDED USE
Planmeca Promax 3D, is a three dimensional Cone Beam Computed Tomography (CBCT) x-ray system, which is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations. The device is to be operated and used by dentists and other legally qualified professionals.

PRODUCT DESCRIPTION
The Planmeca Promax 3D is in principle a conventional digital panoramic x-ray system with three-dimensional Cone Beam Computed Tomography (CBCT) system add on. The product rotates around the patient and takes still images with a flat panel sensor synchronized to x-ray generator pulsing. A 3D reconstruction engine calculates the cylindrical 3-dimensional volume image, which then is viewed in 3D viewing stations.

SUBSTANTIAL EQUIVALENCE

We consider this product modification including a new 3D CBCT x-ray system to be similar in design, composition and function to the following device introduced into commercial distribution after May 28, 1976:

K052587 3D Accu-i-tomo XYZ Slice View Tomograph

The comparison of characteristics supports substantial equivalence. Planmeca Promax 3D is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2006

Mr. Lars Moring
Regulatory Affairs Manager
Planmeca Oy
Asentajankatu 6
FI-00880 Helsinki
FINLAND

Re: K060328
Trade/Device Name: Planmeca Promax 3D
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: February 7, 2006
Received: February 9, 2006

Dear Mr. Moring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060328

Device Name: Planmeca Promax 3D

Indications For Use:

Planmeca Promax 3D, is a three dimensional Cone Beam Computed Tomography (CBCT) x-ray system, which is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations. The device is to be operated and used by dentists and other legally qualified professionals.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donald C. Jepsen

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060328